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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 664,519	09/18/2000	Michael C. Barney	660005.98757	4670

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 06/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,519

Applicant(s)

BARNEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

1. Claims 1-14 are pending.

Applicants' response filed on March 27, 2002 (Paper No. 7) is acknowledged and has been fully considered.

Rejection Withdrawn

Claim Rejections - 35 USC § 103(a)

2. The previous rejection of claims 1-8 and 12-14 under 35 U.S.C. 103(a) as being unpatentable over Nutter *et al.* (WO 98/11883), is withdrawn in view of applicants' response at pages 1-3 in Paper No. 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are indefinite because of the use of the term "mixtures thereof, and combinations thereof". The term "mixtures thereof, and combinations thereof" renders the claim indefinite, it is unclear what components and how much of each component are in the mixture or combination. Note that Markush group is cited in the claim, thus, open language such as "mixtures thereof, and combinations thereof" should be avoided. Claims 2-8, 10-11, 13 and 14

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are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

4. Claims 2, 10 and 13 are indefinite because of the use of the term "from about 0.2 ppm to about 25 ppm". The term "from about 0.2 ppm to about 25 ppm" renders the claim indefinite, it is unclear whether the concentration of the compound is in the range of 0.2 ppm to 25 ppm as to "from...to..." or outside the range of 0.2 ppm to 25 ppm as to "about....to about...". Deletion of the term "about" is suggested.

Claim Rejections - 35 USC § 102&103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nutter *et al.* (WO 98/11883).

Nutter *et al.* teach beta acids (also known as lupulones) such as hexahydrocolupulone (HHC) are used for killing cancer cells or bacterial cells, and inhibiting their growth (page 4, line 12-page 5, line 10), and a pharmaceutical composition comprising the beta acid and a

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pharmaceutical carrier (page 9, lines 14-22) is used to inhibit the growth of *Staphylococcus Aureus* (page 6, line 27-page 7, line 6). The reference indicates lupulones can be administered to achieve the plasma concentration from 0.5 to 75 μM (page 12, lines 4-6; about 0.2 - 62.5 $\mu\text{g/l}$ using MW 395 of HHC), which corresponds to 0.2 - 62.5 ppm (claims 9-10), and the pharmaceutical composition can be used topically (page 9, lines 23-25; claim 12). Since the concentration of HHC has the cited range of 0.2-25 ppm, it is obvious the compound has the inherent property of inhibiting the growth of *Staphylococcus Aureus* but not the growth of *lactobacillus*.

In response, applicants indicate the claimed invention is drawn to a method of inhibiting or controlling the growth of *Staphylococcus Aureus* without preventing the growth of *lactobacillus* at a specific concentration of hop acids, and Nutter *et al.* teach the hexahydrocolupulones inhibit the growth of *lactobacillus* (page 2 of the response). The argument is partially persuasive because Nutter *et al.* does not indicate a method of inhibiting or controlling the growth of *Staphylococcus Aureus* without preventing the growth of *lactobacillus* using the claimed compounds at a specific concentration, thus, the rejection is withdrawn regarding the method claims. However, the reference does teach a pharmaceutical composition containing the hop acid, which has the inherent property of inhibiting the growth of *Staphylococcus Aureus* but not the growth of *lactobacillus* at the cited concentration as indicated above. Regarding inhibiting the growth of *lactobacillus* by hexahydrocolupulones, Nutter *et al.* merely indicates the prior art (U. S. Patent 5,082,975) has shown the result, where a high concentration of hop acid is used (50-200 ppm, column 7, lines 54-58 of U. S. Patent 5,082,975).

Conclusion

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6. No claims are allowed.

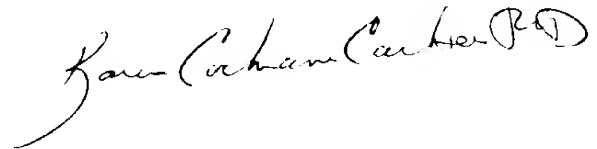
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

June 18, 2002



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER